CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74943

APPROVAL LETTER

ANDA 74-943

AUG 6

Torpharm
A Division of Apotex, Inc.
Attention: Marcy Macdonald, U.S. Agent
Apotex Corp.
50 Lakeview Parkway, Suite 127
Vernon Hills, IL 60061

Dear Madam:

This is in reference to your abbreviated new drug application dated August 16, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Diltiazem Hydrochloride Extended-release Capsules USP, 240 mg.

Reference is also made to your amendments dated November 5, 1997, January 29, February 18, February 27, May 1, and June 1, 1998.

Your application contains a patent certification to patents 4,839,117 and 5,422,123 under Section 505(j)(2)(A)(vii)(IV) of the Act. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Torpharm has complied with the requirements of Section 505(j)(2)(B) of the Act. No action for patent infringement was brought against Torpharm within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Diltiazem Hydrochloride Extended-release Capsules USP, 240 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Dilacor XR® Extended-release Capsules, 240 mg of Rhone Poulenc Rorer Pharmaceuticals, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-040). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-040) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ 8/6/98

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research